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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,605	04/15/2004	Masashige Kuwayama	018961-069	6408

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EXAMINER	
VAINBERG, SIMON	

ART UNIT	PAPER NUMBER
1709	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,605	KUWAYAMA ET AL.	
	Examiner	Art Unit	
	Simon Vainberg	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-3 and 6-11* is/are allowed.

6)☒ Claim(s) *4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/24/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any

inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Vajta et al. reference "Open Pulled Straw (OPS) Vitrification: A New Way to Reduce Cryoinjuries of Bovine Ova and Embryos" in view of Lee et al. (US Patent 6590139) and Kuleshova et al. (A Strategy for Rapid Cooling of Mouse Embryos Within a Double Straw to Eliminate the Risk of Contamination During Storage in Liquid Nitrogen".

5. Regarding claim 4, reference Vajta G. et al. discloses the method comprising the steps of:

preparing egg (bovine ova and embryos) whose intracellular fluid has been replaced with equilibrium fluid and extracellular fluid has been replaced with a vitrified fluid (see pages 53-54, Experiment 1);

collecting egg small-diameter part of egg freezing and storing tube, together with vitrified fluid (see page 54, Fig.1, and paragraph " Experiment 1");

Vajta et al. does not disclose the steps of:

heat-sealing of egg freezing and storing tube at a front portion of small-diameter part and heat-sealing the other side of egg freezing and storing tube at a portion of body part;

mounting a metal protection member on heat-sealed egg freezing and storing tube;

supplying egg freezing and storing tube on which protection member has been mounted into a liquid nitrogen tank.

With respect of step of heat sealing of both sides of tube reference the Lee et al. (US Patent 6590139) teaches heat-sealing of one side of freezing and storing tube and heat-sealing the other said of egg freezing and storing tube (see column 9 lines 45-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to heat-seal the both ends of tube of Vajta reference, which has a body part, and an egg-storing small-diameter part as suggested by Lee et al. because heat-sealing of both ends of the tube provides protection of collected eggs from contamination.

With respect of mounting a metal protection member on heat-sealed egg freezing and storing tube, reference Kuleshova et al. teaches placing a protection member on heat-sealed egg freezing and storing tube; and supplying egg freezing and storing tube on which protection member has been mounted into a liquid nitrogen tank (see pages 2605 and 2606 paragraph "Cryopreservation protocol".

Reference Kuleshova et al. does not disclose a metal protection member on tube, but solves the same protection problem. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Vajta et al. by using a protection member as suggested by

Kuleshova et al. because it eliminates the risk of broking egg storing tube during transfer and storage in liquid nitrogen.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine references Vajita et al., Lee at al. and Kuleshova et al. to develop a method for freezing and storing eggs which reduces or eliminates contamination problems associated with storage in liquid nitrogen and provide protection of the tube.

6. Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Vajta et al. reference "Open Pulled Straw (OPS) Vitrification: A New Way to Reduce Cryoinjuries of Bovine Ova and Embryos" in view of Lee et al. (US Patent 6590139), Kuleshova et al. (A Strategy for Rapid Cooling of Mouse Embryos Within a Double Straw to Eliminate the Risk of Contamination During Storage in Liquid Nitrogen" and Anderson et al. (US Patent 5217693).

7. For claim 5, reference Vajta et al. discloses the step of preparing egg (bovine ova and embryos) whose intracellular fluid has been replaced with equilibrium fluid and extracellular fluid has been replaced with a vitrified fluid (see pages 53-54, Experiment 1).

Vajta et al. does not disclose the steps of:

preparing a unit including egg freezing and storing tube and sucking tool mounted on a body part of egg freezing and storing tube;

heat-sealing of egg freezing and storing tube at a front portion of small-diameter part and heat-sealing the other side of egg freezing and storing tube at a portion of body part;

collecting egg into small-diameter part of egg freezing and storing tube, together with vitrified fluid by operating sucking tool;

heat-sealing of egg freezing and storing tube at a front portion of small-diameter part and heat-sealing the other side of egg freezing and storing tube at a portion of body part with sucking tool mounted on egg freezing and storing tube;

removing sucking tool from egg freezing and storing tube;

mounting a metal protection member on heat-sealed egg freezing and storing tube; and

supplying egg freezing and storing tube on which protection member has been mounted into a liquid nitrogen tank.

With respect to step of preparing a unit, reference Anderson et al. (US Patent 5217693) teaches preparing a unit including egg freezing and storing tube and sucking tool mounted on a body part of egg freezing and storing tube (see Fig.1).

With respect to step of collecting egg, reference Anderson et al. (US Patent 5217693) teaches collecting egg in lower part of tube, together with storage fluid by operating sucking tool (see Fig.1 and column 3 lines 61-68). Anderson et al. refers to uniform tube. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the tube from reference Vajta et al. to collect egg into small-diameter part of the tube with vitrified fluid by operating sucking tool according the reference Anderson et al.

because it allows to facilitate the process of freezing and protect sterility of the egg.

With respect of step of heat sealing of both sides of tube reference the Lee et al. (US Patent 6590139) teaches heat-sealing of one side of freezing and storing tube and heat-sealing the other said of egg freezing and storing tube (see column 9 lines 45-50).

Reference Anderson et al. teaches that the sucking tool mounted on egg freezing and storing tube (see Fig.1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to heat-seal the both ends of the tube of Vajta reference according to reference Lee et al. with sucking tool mounted on the tube according to Anderson reference to eliminate contamination of egg.

With respect to step of removing sucking tool reference Anderson et al. (US Patent 5217693) teaches removing sucking tool from egg freezing and storing tube (see column 2 lines 2-5).

With respect of mounting a metal protection member on heat-sealed egg freezing and storing tube reference Kuleshova et al. teaches placing a protection member on heat-sealed egg freezing and storing tube; and supplying egg freezing and storing tube on which protection member has been mounted into a liquid nitrogen tank (see pages 2605 and 2606 paragraph "Cryopreservation protocol".

Reference Kuleshova et al. does not disclose a metal protection member on tube, but solves the same protection problem. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a metal member to protect the tube before immerse it into liquid nitrogen because that significantly increases the cooling rate due to high termoconductivity of metal compared with plastic and provides more reliable protection.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine references Vajta et al., Lee at al., Anderson et al. and Kuleshova et al. to develop a method for freezing and storing eggs which comprise procedure for filling tube, eliminates or reduces contamination problems associated with storage in liquid nitrogen and provide protection of the tube.

Allowable Subject Matter

1. Claims 1-3 and 6-11 are allowed.

2. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claim 1 the prior art record does not disclose egg freezing and storing instrument comprising a metal cylindrical protection member for protecting egg freezing and storing tube,

wherein said cylindrical protection member has a tubular part for accommodating said front side of said small-diameter part of said egg freezing and storing tube;

and a semi-tubular part for accommodating a portion of said small-diameter part of said egg freezing and storing tube not accommodated in said tubular part and a front portion of said body part.

With respect to claim 6 the prior art record does not disclose a metal cylindrical protection member mounted on said egg freezing and storing tube, for protecting said egg freezing and storing tube, wherein said cylindrical protection member has a tubular part for accommodating said front side of side small-diameter part of said egg freezing and storing tube; a semi-tubular part, disposed at a rear end of the tubular part, for accommodating a portion of said small-diameter part of said egg freezing and storing tube not accommodated in said tubular part and a front portion of said body part; and a holding part, disposed at a rear end of said semi-tubular part, for holding said body part of said egg freezing and storing tube, said cylindrical protection member is slidable to a rear side of said egg freezing and storing tube to allow said small-diameter part to be exposed to the outside from a front end of said cylindrical protection member; and
said egg freezing and storing tube has a slip-off prevention part, for preventing said cylindrical protection member from slipping off front said egg freezing and storing tube, formed on said body part thereof or in the vicinity of a boundary between said body part thereof and said small-diameter part thereof.

With respect to claims 10 and 11 the prior art record does not disclose a metal cylindrical protection member being slidable to a rear side of said egg freezing

and storing tube to allow said small-diameter part to be exposed to the outside from a front end of said cylindrical protection member, and said egg freezing and storing tube has a slip-off prevention part for preventing said cylindrical protection member from slipping off from said egg freezing and storing tube. The prior art also does not suggest exposing said small-diameter part of said egg freezing and storing tube to the outside by sliding said cylindrical protection member to a rear side of said egg freezing and storing tube; accommodating said small-diameter part of said egg freezing and storing tube in said cylindrical protection member by sliding said cylindrical protection member to a front side of said egg freezing and storing tube after said one side of said egg freezing and storing tube is sealed or both said one side of said egg freezing and storing tube and a portion of said body part are sealed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon Vainberg whose telephone number is 571-270-3150. The examiner can normally be reached on Monday-Thursday from 7:30 – 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SV
04-18-2007

WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER